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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,700	01/09/2003	Robert Paul Anderson	HO-P02416USO	2705
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COZEN O' CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508				
			EXAMINER SAUNDERS, DAVID A	
			ART UNIT 1644	PAPER NUMBER

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/089,700

Applicant(s)

ANDERSON ET AL.

Examiner

David A. Saunders, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 112-163 is/are pending in the application.
- 4a) Of the above claim(s) 120-122, 124-127, 132-135, 139-142 and 152-163 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 112-115 is/are allowed.
- 6) ☒ Claim(s) 116-119, 123, 128-131, 136-138 and 143-151 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Amendment of 1/27/06 has been entered. Claims 112-163 are pending. Claims 112-119, 123, 128-131, 136-138 and 143-151 are under examination.

The amendment has entered no new matter.

The following corrections pertain to the previous Office action:

On PTO-326, under **Disposition of Claims**, "112-165" should have read as --112-163--.

At page(s) 5, line 3 "14" should have read as --24--.

The amendment has overcome previously stated issues as follows:

The objection to the specification.

The rejection of claims 138 and 146 under 35 USC 112, 2<sup>nd</sup> paragraph.

The rejection of claim 129 under 35 USC 112, 2<sup>nd</sup> paragraph, with respect to the recitation of "composition".

The rejection of claims 116-117, 128-131, 136-138 and 143-151 under 35 USC 112, 1st paragraph, with respect to the enablement/how to use provision. It is deemed that applicant has taught one of skill how to use any composition that is supported by the original disclosure. The 112 rejections will therefore be maintained infra, only under the description provision of 35 U.S.C. 112, first paragraph.

The rejection of claims 112-117, 119 and 128 under 35 USC 101.

The following rejections of record are maintained or modified as follows:

Claims 123, and 128-131 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 123, 128 and 129 the definition of "analogue" is confusing.

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The examiner will not accept applicant's urgings that these claims are clear because each of these claims recite an "analogue of a peptide comprising the amino acid sequence SEQ ID NO:1". This phrase is indefinite because it can be read two ways: 1) the analogue includes a peptide that is exactly the same as SEQ ID NO:1, to which peptide or non-peptide substituents can be added to the C- or N- terminals or to any side chain R-group within SEQ ID NO:1 or 2) the analogue includes a peptide that has SEQ ID NO:1 altered in some way.

Claims 116-119, 128-131, 136-138 and 143-151 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite new matter for reasons of record.

Claims 116 and 118, as well as all their dependent claims except 119, contain new matter by reciting "and other/gliadin/non-gliadin sequence" without limiting the other sequence to one that is fused. Applicant considers that original claim 3 supports claims 116 and 118, by virtue of reciting that the Peptide of SEQ ID NO:1 is bound to an HLA molecule. The examiner deems that one of skill would narrowly interpret "bound" in this context to mean non-covalently complexed, as in the case when an epitopic peptide naturally binds to an HLA receptor molecule. This recitation in claim 3 does not support what is now recited in claims 116 and 118, because what is being claimed is a peptide per se, not a complex of a peptide with some other peptide/protein. Further, even if a complex of a peptide bound to an HLA molecule were considered as being suggestive of what is recited in claims 116 and 118, it is deemed that claims

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116 and 118 encompass much that goes beyond such suggestion – e.g. complexes of the peptide with other peptides/proteins which are not HLA, or even MHC, and covalent conjugates of the peptide with HLA or other peptides/proteins.

Also, the examiner finds no description for the fusion of SEQ ID NO: 1 to another gliadin sequence, as in claims 116-117 and in claim 128, lines 2-15 and claim 129, Lines 3-17. The examiner only finds support for fusion of SEQ ID NO: 1 to a non-gliadin sequence (page 10, lines 15-17). In the case where there is fusion to another gliadin sequence (or more than one Thereof, it appears that the fusion is of a mutated form of the disclosed sequences (e.g. SEQ ID NO: 1 of 2) to the gliadin sequence. See page 22, lines 3-12. Applicant is thus claiming more embodiments than originally disclosed. Dependent claims 119, 136-138 and 143-151 are included in this rejection.

Applicant has urged that page 11, lines 24-31 support; however, as noted previously, the examiner finds that this para. is referring to a composition of multiple agents, rather than to a fusion protein or a conjugate of the multiple agents. The natural reading of the statement that the “agent may be a product defined by at least 2, 5, 10 or 20 agents as defined...” is that this is a composition mixture of multiple agents, particularly in view of the fact that page 11, line 25 further recites, that “typically the composition comprises...” and that nothing in the rest of the para. refers to any fusion sequences. Applicant is reminded that the word “compositions” requires that there be two or more compounds as components, not one compound having two components fused. Applicant is wishing for this paragraph to support an embodiment that is

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more explicit than what was originally conveyed. Furthermore, even if it could be considered that recitation of "at least 2, 5, 10 or 20 agents" conveys these in a fusion protein, it is noted that Page 23, line 27 to page 24, line 5 offers nothing to support, since this para. is referring to a polynucleotide encoding "the sequence of SEQ ID NO: 1 or 2 or any of the agents mentioned herein" in the alternative and states nothing about a polynucleotide encoding multiple epitopic sequences from different gliadin proteins. Applicant's argument is that these various passages should be "taken together" to provide support. When one interprets the passages "taken together" there might be some stretched basis for obviousness of, but not an explicit basis for describing, what is now claimed; applicant is reminded that what might be obvious fails to provide a basis for description. *Lockwood V. American Airlines* 41 USPQ2d 1961. Furthermore, while one might be able to piece together various portions of applicant's disclosure to come up with a new subgenus of agents, this cannot provide a basis for written description of a new subgenus that was not particularly pointed out. See *In re Ruschig* 154 USPQ 118, *Irikura v. Petersen* 18 USPQ2d 1362, and *Fuijikawa v. Wattanasin* 39 USPQ2d 1895; in these cases there was found to be lack of support for a new subgenus of compounds, which one could have pieced together from various aspects of a genus of compounds presented in a Markush formula but which had not been specifically pointed out as an aspect of the invention.

Applicant has further urged that Page 23, line 27 to page 24, line 5 provide teachings inclusive of SEQ ID NO:1 per se and not merely a mutant thereof. The examiner concurs (see page 24, line 2); however, whatever it may be that is supposed to be encoded "To the 5' and 3' of this coding sequence" that may be "different from the sequence or codons 5' and 3' to these sequences in the corresponding gliadin gene" (page 24, lines 3-5) has not been specifically

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pointed out in accord with the embodiment now recited in claims 116-117 and 128-129. To the contrary, the examiner finds that what has been contemplated as being "To the 5' and 3' of this coding sequence" has been set forth at page 24, lines 6-12 as mere "bread and butter" sequences that are commonly present in various expression vectors used in recombinant technology.

Applicant's arguments filed 1/27/06 have been fully considered but they are not persuasive for the above reasons.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

This application contains claims 120-122, 124-127, 132-135, 139-142 and 152-163 drawn to an invention nonelected with traverse in the Paper filed on 9/13/04. A complete reply

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to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 4/13/06 DAS

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
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